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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,016	07/30/2003	Bret A. Ferree	BAF-14702/29	7766

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EXAMINER

AFREMOVA, VERA

ART UNIT PAPER NUMBER

1651

DATE MAILED: 05/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/630,016	<b>Applicant(s)</b> FERREE, BRET A.	
	<b>Examiner</b> Vera Afremova	<b>Art Unit</b> 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 05 November 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>11/05/2003</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Claims 1-22 are pending and under examination.

#### ***Claim Rejections - 35 USC § 112***

Claims 1-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rendered indefinite by the phrase “benefiting” since it does not appear to point out the benefits as intended or any other active steps, if intended.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8, 10-12 and 18-22 are rejected under 35 U.S.C. 102(b or e) as being anticipated by US 6,463,933 (Laster et al.) or WO 98/42270.

US 6,463,933 (Laster et al.) and WO 98/42270 are identical in their disclosure and, therefore, only US 6,463,933 is discussed below. The same rejection is applied to the claims as being anticipated by WO 98/42270.

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Claims are directed to a method of developing biologic material comprising step of injecting or surgically implanting non-bone cells or tissue into bone(s) of a vertebrate, thus, benefiting from the non-bone cells after receiving nourishment from the blood vessels within the bone. Some claims are further drawn to the non-bone cells or tissue that are islets cells harvested from pancreas of animal donor. Some claims are further drawn to the use of extracellular matrix scaffold in conjunction with the cells including gel and to the use of additional factors including VEGF. Some claims are further drawn to the bone site for cell implantation that is pelvis or tibia or femur. Some claims are further drawn to implanting the cells into the bone through a window created in cortical bone layer and closing the window with seal after cell implantation.

US 6,463,933 recognizes bone or bone marrow as a beneficial site for cell implantation that provides easy access to the host circulatory system and as an immune privileged site that eliminates host immune response to the implanted cells or materials (col. 4, lines 5-14). US 6,463,933 discloses a method of developing biologic material comprising step of injecting or surgically implanting non-bone cells including hepatocytes and/or pancreatic islets into bone(s) of a vertebrate (col. 6, line 5-6). The vertebrate is a mammalian animal of any age including fetus (col. 5, lines 40-41). The cells are implanted in conjunction with extracellular matrix scaffold including gel or fiber implants (col. 6, lines 12-13) and with additional factors including VEGF (col. 7, line 31). The site for cell implantation is iliac crest that is a dorsal bone of the pelvis (col. 8, line 19) and the other bone sites such as skull, ribs, etc. (col. 8, lines 34-38). In a particular example, US 6,463,933 discloses implanting islets cells into the tibia through a window or a whole created in cortical bone layer to access bone marrow and closing the window with a seal after cell implantation (col. 10, lines 10-20). US 6,463,933 discloses that islets cells and/or

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diabetic host animals had benefits and that transplanted islets or beta cells survived for at least 30 days (col. 12, lines 43-45).

Thus, the cited patent US 6,463,933 anticipates the claimed invention.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,463,933 (Laster et al.) or WO 98/42270 taken with US 5,762,959 (Soon-Shiong et al.) and US 4,904,260 (Ray et al.).

Claims 1-8, 10-12 and 18-22 as explained above. Some claims are further drawn to a human donor. Some claims are further drawn to the use of a porous bag for implantation of cells and/or additional factors into the bone(s).

US 6,463,933 (Laster et al.) or WO 98/42270 is/are relied upon as explained above.

Although in a particular example US 6,463,933 (Laster et al.) discloses rats as donors and hosts of cells in the method for implantation of non-bone cells into bones, the cited patent clearly teaches this method is suitable for any mammalian animals and, thus suitable for humans.

US 6,463,933 (Laster et al.) teaches the use of extracellular matrix scaffold including gel or fiber implants for delivery and implantation of cells and factors. But it appears to lack disclosure about a porous bag for implantation of cells and/or additional factors into the bone(s).

However, porous bags for implantation of cells and/or additional factors into the bone(s) are known in the prior art.

For example: US 5,762,959 (Soon-Shiong et al.) teaches a porous beg or a capsule for encapsulation and surgical delivery of cells or islets into hosts wherein the capsule allows for diffusion of active material out of the capsule (abstract) but prevents access by immune cells and/or has strong immunoprotective effects (col. 10, lines 52; col. 19, lines 29-40; col. 20, lines 4-6).

US 4,904,260 (Ray et al.) also teaches a porous bag or a capsule with semi-permeable membrane with pores for delivery of therapeutic materials into bones including disc of human spine (whole document including abstract and col.4, lines 3-20).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to use a porous bag for implantation of cells and/or additional factors into the bone(s) with a reasonable expectation of success in delivering cells and factors into bone implantation sites because the bags or capsules as claimed are know in the prior art and have been taught and/or suggested for delivery of therapeutic materials including islets into implantations sites including bones as adequately demonstrated by the cited references. One of skill in the art would have been motivated to use porous bags or semi-permeable capsules for the expected benefits in allowing long-term release of diffusible therapeutic materials and in providing strong immunoprotective effects from immune cells of hosts. Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

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The claimed subject matter fails to patentably distinguish over the state art as represented by the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926.

The fax phone number for the TC 1600 where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology center 1600, telephone number is (571) 272-1600.

Vera Afremova

AU 1651

May 12, 2005

A handwritten signature in black ink, appearing to read 'V. Afremova', with a long horizontal line extending to the right.

VERA AFREMOVA

PRIMARY EXAMINER

(FILE 'HOME' ENTERED AT 18:34:30 ON 04 MAY 2005)

FILE 'MEDLINE' ENTERED AT 18:34:46 ON 04 MAY 2005

L1        5 S ISLET(P)(BONE)(P)SITE(P)(TRANSPLANT? OR IMPLANT? OR INJECT? OR  
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FILE 'BIOSIS' ENTERED AT 18:40:51 ON 04 MAY 2005

L2        4 S ISLET(P)(BONE)(P)SITE(P)(TRANSPLANT? OR IMPLANT? OR INJECT? OR  
ADMINISTR?

FILE 'ADISCTI, ADISINSIGHT, ADISNEWS, AGRICOLA, ANABSTR, ANTE, AQUALINE,  
AQUASCI, BIOBUSINESS, BIOCOMMERCE, BIOENG, BIOSIS, BIOTECHDS, BIOTECHNO,  
CABA, CANCERLIT, CAPLUS, CEABA-VTB, CEN, CIN, CONFSCI, CROPB, CROPU,  
DDFB, DGENE, DISSABS, DRUGB, DRUGMONOG2, ...' ENTERED AT 18:43:25 ON 04  
MAY 2005

L3        81 S ISLET(P)(BONE)(P)SITE(P)(TRANSPLANT? OR IMPLANT? OR INJECT? OR  
ADMINISTR?

L4        54 DUPLICATE REMOVE L3 (27 DUPLICATES REMOVED)